

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: William C. Brunnett et al. Examiner: David C. Comstock
Serial No.: 10/776,835 Group Art Unit: 3733
Filed: February 11, 2004 Docket No.: M190.147.101 / PD266.00
Title: HIGH SPEED SURGICAL CUTTING INSTRUMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R § 1.132

Sir/Madam:

I, Scott Carpenter, hereby declare that:

1. I currently reside at 1030 Buddy Crout Lane, Neptune Beach FL 32266.
2. I have earned an associates in science degree in nursing from Florida Community College in Jacksonville.
3. My previous employment history includes surgical nursing, clinical product support and product management. I've been employed with Medtronic Xomed, Inc. ("Xomed"), in several marketing roles since February 1999. My current title is Product Manager, Powered Rhinology. In this capacity, I market and sell high powered drills and accessories to hospitals, clinics and doctors.

4. My current employment capacity provides me with an intimate knowledge of various surgical operations that utilize high speed surgical cutting instruments. In particular, I have knowledge of cochlear implant procedures and the iatrogenic risks associated with the cochleostomy portion of this procedure. I also have the opportunity to witness these procedures being performed and discuss these procedures with doctors that perform the procedures.

5. I have reviewed and understand the contents of the present application as described in U.S. Patent Application Publication No. 2005/0177168 ("the '168 Publication"). Additionally, I have reviewed and understand the claims set forth in the Amendment that is filed herewith.

6. Features described in the '168 Publication and recited in the present claims are marketed and sold by Xomed under the Visao® brand name. Attached as Exhibit A is a document titled "The Visao® High-Speed Otologic Drill Catalog". The catalog, Exhibit A, describes curved burs that operate at high speeds for cochleostomies, middle fossa acoustic

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neuromas and infralabyrinth approaches to the petrous apex. In particular, the curved burs in the catalog embody features recited in the claims of the present application. For example, claim 1 recites an instrument having a curved segment that allows rotation of an inner wire at a speed in excess of 50,000 RPM. These features are prominent in Xomed's marketing initiatives and have enjoyed commercial success.

7. Attached as Exhibit B is revenue data for sales in the United States of Visao® drills and burs. Drill revenue is denoted as "Capital" and bur revenue is denoted as "Disposable". In the second quarter of fiscal year 2004, since the introduction of curved burs, revenue for bur sales have steadily increased. For example, bur revenue in fiscal year 2004 was \$1.8 million and bur revenue in fiscal year 2008 was \$4.6 million. Thus, in a period of five years, bur revenue has more than doubled.

8. Attached as Exhibit C is a chart showing the number of drills and the number of curved burs sold by Xomed from the second quarter of fiscal year 2005 to the fourth quarter of fiscal year 2008. Sale volumes have risen steadily over the time period shown. For example, for a period from Quarter 2, 2005 to Quarter 4, 2005, the volume of curved burs were less than 200 for each quarter. In contrast, for a period from Quarter 2, 2008 to Quarter 4, 2008, the volume of curved burs were more than 1,000 for each quarter.

9. With particular reference to cochlear implant procedures, curved bur sales have established significant market share increases for a period from calendar year 2005 to calendar year 2007. Exhibit D shows a chart of cochlear implant procedures relative to Visao® curved bur sales. In particular, calendar year 2007 figures show that Visao® curved burs from Xomed were used in nearly half of cochlear implant procedures performed in the U.S.

10. Based on the above, as well as evidence presented in the Exhibits attached hereto, it is my belief that the Visao® curved bur has produced substantial commercial success in the marketplace relative to other burs. In particular, the curved bur and high operational speeds of Visao® products has provided substantial commercial success.

Declaration under 37 C.F.R. § 1.131

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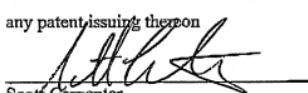
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11. I declare that all statements made herein are my own knowledge and are true and that all statements made on information are believed to be true; and further, that these statements are made with the knowledge that willful, false statements and the like so-made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon



Scott Carpenter

August 25th, 2008
Date



THE VISAO® HIGH-SPEED OTOLOGIC DRILL CATALOG

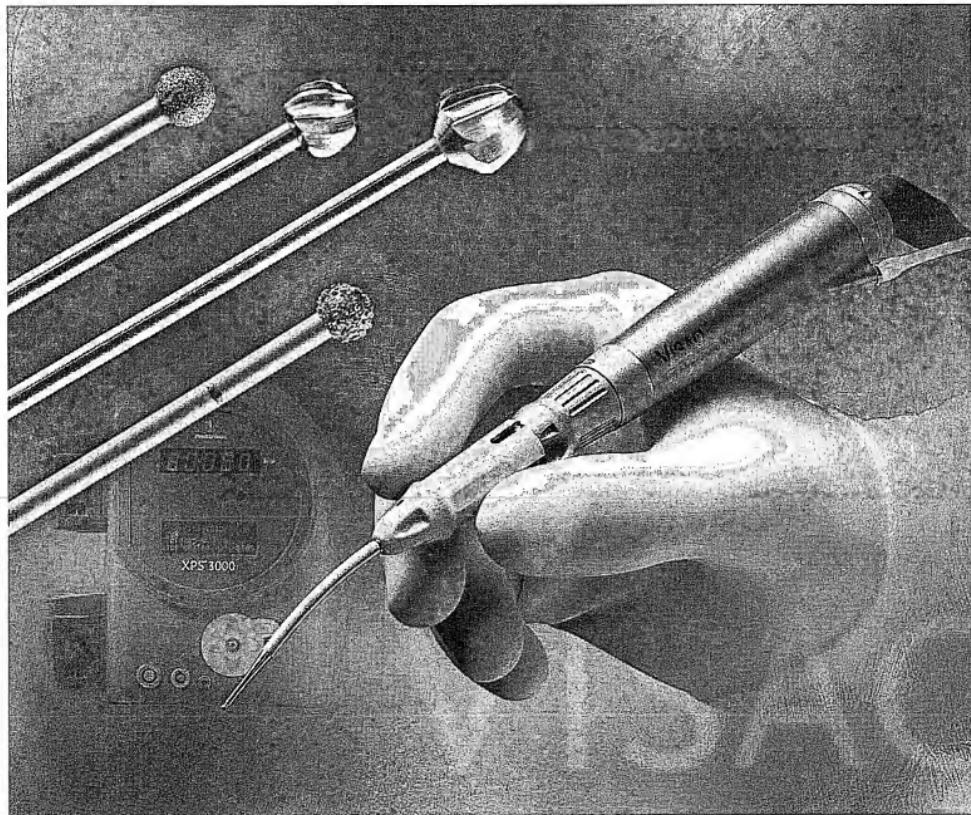


EXHIBIT A

Visao® High-Speed Otologic Drill with the XPS® 3000 System

Revolutionary design for neurotology

The Visao® High-Speed Otologic Drill allows remarkable surgical visibility and access with patent-pending curved burs... just what you need for cochleostomies, middle fossa acoustic neuromas and infralabyrinth approaches to the petrous apex.

The Visao drill's 80,000 rpm and high torque allow for delicate, precise removal of bone and tissue with virtually no start-up "kick."

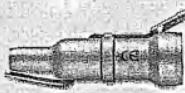
The lightweight, ergonomic titanium exterior provides a well-balanced, comfortable handpiece with low operating temperatures and integrated water-cooling.

Exhibit A

The Visao® High-Speed Otologic Drill utilizes an adjustable irrigation collar, as well as irrigating and non-irrigating bur guards for straight burs.



33-34610 Irrigation Collar

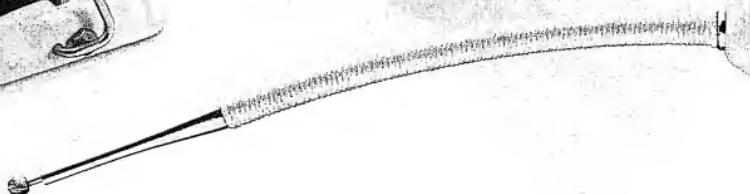
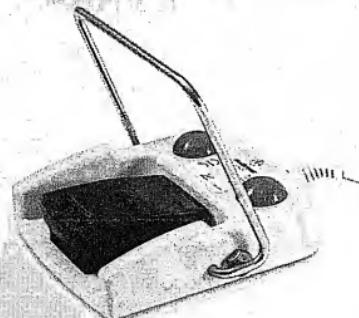
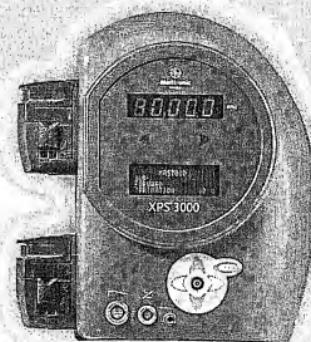


33-34635 Extended Bur Guard
with Irrigation



33-34625 Extended Bur Guard
without Irrigation

- High-speed curved burs in various sizes help provide better visibility and access
- High-speed curved burs feature an outer, non-rotating tube design to help protect critical anatomy from mechanical injury
- 80,000 rpm forward and reverse operation provides power in debulking operations and finesse in delicate procedures
- Electric motor reduces industrial noise compared to traditional pneumatic handpieces



high-speed cochleostomy burs

high-speed cochleostomy burs

- Innovative, 20° curved design
- 1 per box
- Use at speeds up to 80,000 rpm

Curved Fluted Cutting Burs

Bur
Diameter
(mm)

S H A F T L E N G T H

98mm

1.5

31-151598E

1

31-151098E

Curved Fine Diamond Burs

Bur
Diameter
(mm)

S H A F T L E N G T H

98mm

1.5

31-181598E

1

31-181098E

0.6

31-180698E

0.5

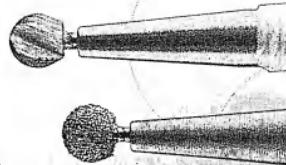
31-180598E

The revolutionary 20° curved burs allow better visibility and access to the surgical field during complex procedures with only small access holes or speculums. Each bur's thin outer sheath leaves very little rotating shaft exposed, which helps protect delicate tissue from a spinning shaft.

high-speed curved burs

high-speed curved burs

- Innovative, 20° curved design
- 1 per box
- Use at speeds up to 80,000 rpm



Curved Fluted Cutting Burs	Bur Diameter (mm)	SHAFT LENGTH
		90mm 115mm
	2	31-152090E 31-1720115E
	1.5	31-1715115E
	1	31-1710115E

Curved Fine Diamond Burs	Bur Diameter (mm)	SHAFT LENGTH
		90mm 115mm
	2	31-182090E 31-1920115E

Curved Coarse Diamond Burs	Bur Diameter (mm)	SHAFT LENGTH
		90mm 115mm
	2	31-202090E 31-2120115E

round steel burs

• 5 per box

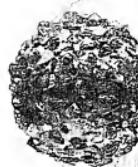
• Use at speeds up to 80,000 rpm

Bur Diameter (mm)	Bur Type	Part Number	Bur Length
7	Standard	31-317045U	52mm
	Medium*	31-317057U	64mm
	Long*	31-317062U	69mm
6	Standard	31-316046U	52mm
	Medium*	31-316058U	64mm
	Long*	31-316063U	69mm
5	Standard	31-315047U	52mm
	Medium*	31-315059U	64mm
	Long*	31-315066U	71mm
4	Standard	31-314053U	57mm
	Medium*	31-314065U	69mm
	Long*	31-314068U	72mm
3.5	Standard	31-313553U	57mm
	Long*	31-313568U	72mm
3	Standard	31-313054U	57mm
	Long*	31-313069U	72mm
	X-Long*	31-12974C	78mm
2.5	Standard	31-312554	57mm
	Long*	31-312569	72mm
2	Standard	31-312055	57mm
	Long*	31-312070	72mm
	X-Long*	31-142075	77mm
1.5	Standard	31-311555	57mm
	Long*	31-311570	72mm
	X-Long*	31-141575	77mm
1	Standard	31-311056	57mm
	Long*	31-311071	72mm
	X-Long*	31-141075	76mm

*Requires bur guard

round coarse diamond burs

round coarse diamond burs



- 1 per box
- Use at speeds up to 80,000 rpm

Bur Diameter (mm)	Bur Type	Part Number	Bur Length
6	Standard	31-116050	56mm
	Medium	31-116058	64mm
	Long*	31-116065	71mm
5	Standard	31-115051	56mm
	Medium	31-115059	64mm
	Long*	31-115066	71mm
4	Standard	31-114053	57mm
	Medium	31-114065	69mm
	X-Long*	31-114075	79mm
3.5	Standard	31-113554	57mm
	Long*	31-113568	72mm
3	Standard	31-113054	57mm
	Long*	31-113069	72mm
	X-Long*	31-113075	78mm
2.5	Standard	31-112554	57mm
	Long*	31-112569	72mm
	X-Long*	31-112575	78mm
2	Standard	31-112055	57mm
	Long*	31-112070	72mm
	X-Long*	31-112075	77mm
1.5	Standard	31-111555	57mm
	Long*	31-111570	72mm
	X-Long*	31-111575	77mm
1	Standard	31-111056	57mm
	Long*	31-111071	72mm
	X-Long*	31-111075	76mm

*Requires bur guard

round fine diamond burs

round fine diamond burs

• 1 per box

• Use at speeds up to 80,000 rpm

Bur Diameter (mm)	Bur Type	Part Number	Bur Length
6	Standard	31-136050	56mm
	Medium	31-136058	64mm
	Long*	31-136065	71mm
5	Standard	31-135051	56mm
	Medium	31-135059	64mm
	Long*	31-135066	71mm
4	Standard	31-134053	57mm
	Medium	31-134065	69mm
	Long*	31-134068	72mm
3.5	Standard	31-133553	57mm
	Long*	31-133568	72mm
3	Standard	31-133054	57mm
	Long*	31-133069	72mm
	X-Long*	31-103075	78mm
2.5	Standard	31-132554	57mm
	Long*	31-132569	72mm
	X-Long*	31-102575	78mm
2	Standard	31-132055	57mm
	Long*	31-132070	72mm
	X-Long*	31-102075	77mm
1.5	Standard	31-131555	57mm
	Long*	31-131570	72mm
	X-Long*	31-101575	77mm
1	Standard	31-131056	57mm
	Long*	31-131071	72mm
	X-Long*	31-101075	76mm
0.5	Standard	31-130556	57mm
	Long*	31-130571	72mm
	X-Long*	31-100575	76mm

*Requires bur guard



ordering information

33-33616	Visao® High-Speed Otologic Drill - System 16
33-18503	Xcalibur® Irrigation Tubing Set, Sterile, 4/box
33-18506	Xcalibur High-Speed Drill Coolant Tubing Set, 2/box
33-34800	Visao High-Speed Otologic Drill
33-34625	Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation
33-34635	Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation
33-34610	Visao High-Speed Otologic Drill Irrigation Sleeve Assembly
33-34895	Visao High-Speed Otologic Drill Sterilization Tray
33-33617	Visao High-Speed Otologic Drill, IGS Trackable - System 17
33-18503	Xcalibur Irrigation Tubing Set, Sterile, 4/box
33-18506	Xcalibur High-Speed Drill Coolant Tubing Set, 2/box
33-34800T	Visao High-Speed Otologic Drill, IGS Trackable
33-34625	Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation
33-34635	Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation
33-34610	Visao High-Speed Otologic Drill Irrigation Sleeve Assembly
33-34895	Visao High-Speed Otologic Drill Sterilization Tray
33-33618	Visao High-Speed Otologic Drill and XPS 3000 Console - System 18
33-18503	Xcalibur Irrigation Tubing Set, Sterile, 4/box
33-18506	Xcalibur High-Speed Drill Coolant Tubing Set, 2/box
33-34800	Visao High-Speed Otologic Drill
33-34625	Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation
33-34635	Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation
33-34610	Visao High-Speed Otologic Drill Irrigation Sleeve Assembly
33-34895	Visao High-Speed Otologic Drill Sterilization Tray
18-97102	XPS® 3000 Console, Two Pumps
18-97821	Power Cord, 6 meters
18-95420	Multi-Function Footswitch, Single Pedal
18-97510	XPS IV Pole Basket for Footswitch
18-97019	XPS 3000 Straightshot™ M4 Microdebrider, Visao High-Speed Drill and XPS 3000 Console - System 19
18-97102	XPS 3000 Console, Two Pumps
18-98200T	XPS Straightshot M4 High-Speed IGS-Trackable Microdebrider
18-97821	Power Cord, 6 meters
18-95420	Multi-Function Footswitch, Single Pedal
18-97510	XPS IV Pole Basket for Footswitch
18-98400	XPS Straightshot M4 Sterilization Tray
33-18503	Xcalibur Irrigation Tubing Set, Sterile, 4/box
33-18506	Xcalibur High-Speed Drill Coolant Tubing Set, 2/box
33-34800	Visao High-Speed Otologic Drill
33-34625	Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation
33-34635	Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation
33-34610	Visao High-Speed Otologic Drill Irrigation Sleeve Assembly
33-34895	Visao High-Speed Otologic Drill Sterilization Tray

ordering information

ordering information

18-97020	XPS 3000 Straightshot M4 Microdebrider, Visao High-Speed Drill, Skeeter® and XPS 3000 Console - System 20
18-97102	XPS 3000 Console, Two Pumps
18-98200T	XPS Straightshot M4 High-Speed IGS-Trackable Microdebrider
18-97821	Power Cord, 6 meters
18-95420	Multi-Function Footswitch, Single Pedal
18-97510	XPS IV Pole Basket for Footswitch
18-98400	XPS Straightshot M4 Sterilization Tray
33-18503	Xcalibur Irrigation Tubing Set, Sterile, 4/box
33-18506	Xcalibur High-Speed Drill Coolant Tubing Set, 2/box
33-34800	Visao High-Speed Otologic Drill
33-34625	Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation
33-34635	Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation
33-34610	Visao High-Speed Otologic Drill Irrigation Sleeve Assembly
33-34895	Visao High-Speed Otologic Drill Sterilization Tray
30-55601	Skeeter® Ultralite Handpiece
31-55615	Skeeter Sterilization Tray
18-97021	XPS 3000 Visao High-Speed Drill, Skeeter and XPS 3000 Console - System 21
18-97102	XPS 3000 Console, Two Pumps
18-97821	Power Cord, 6 meters
18-95420	Multi-Function Footswitch, Single Pedal
18-97510	XPS IV Pole Basket for Footswitch
33-18503	Xcalibur Irrigation Tubing Set, Sterile, 4/box
33-18506	Xcalibur High-Speed Drill Coolant Tubing Set, 2/box
33-34800	Visao High-Speed Otologic Drill
33-34625	Visao High-Speed Otologic Drill Extended Bur Guard without Irrigation
33-34635	Visao High-Speed Otologic Drill Extended Bur Guard with Irrigation
33-34610	Visao High-Speed Otologic Drill Irrigation Sleeve Assembly
33-34895	Visao High-Speed Otologic Drill Sterilization Tray
30-55601	Skeeter Ultralite Handpiece
31-55615	Skeeter Sterilization Tray

For further information, please call Medtronic ENT at 800.874.5797 or 904-296-9600.

You may also consult our website at www.MedtronicENT.com.

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Canada: 1-800-217-1617	Luxembourg: 32-2456-09-09
China: 86-21-50800998	Netherlands: 31-45-566-8371
France: 33-470-679-800	Poland: 48-22-465-9442
Germany: 49-211-5293-209	Singapore: 65-6776-6255
Hong Kong: 852-2919-1312	Spain: 34-91-625-05-40
India: 91-22-26836733	UK: 44-1923-205-166
Italy: 39-02-24137-324	USA: 1-904-296-9600
Japan: 81-6-4795-1506	



Medtronic

Alleviating Pain • Restoring Health • Extending Life

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HEART AND VASCULAR DISEASE • NEUROLOGICAL DISORDERS • PAIN • SPINAL DISORDERS • DIABETES
UROLOGIC DISORDERS • DIGESTIVE SYSTEM DISORDERS • EYE, EAR, NOSE AND THROAT DISORDERS

Domestic Drill Business

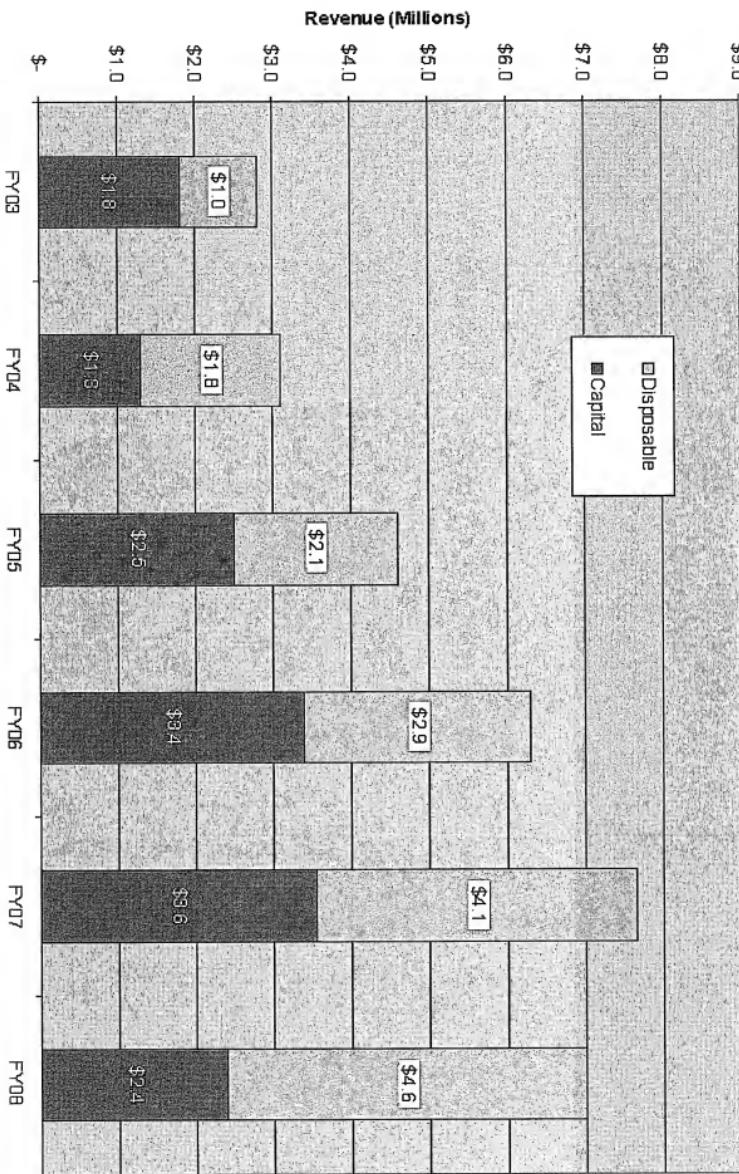
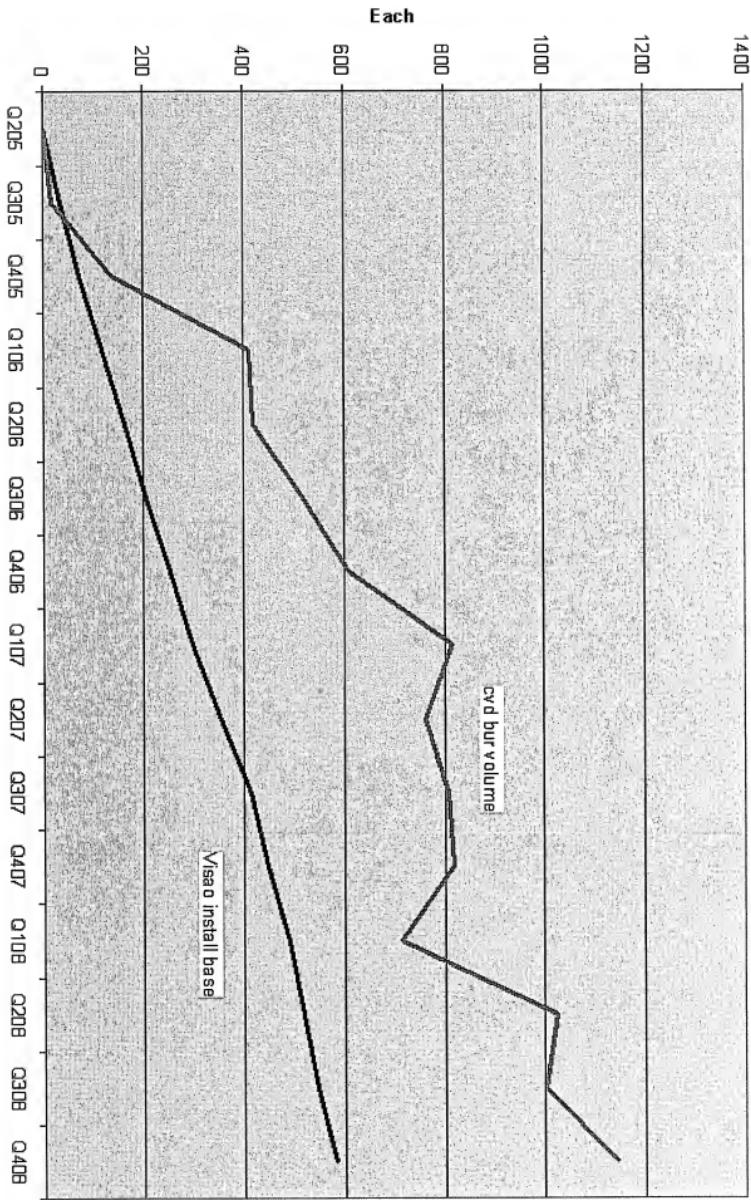


EXHIBIT B

Quarterly Installed base & curved bur volume

**EXHIBIT C**

**Cochlear Implant Procedures
& Relative Medtronic ENT Curved Bur Sales
(USA Only)**

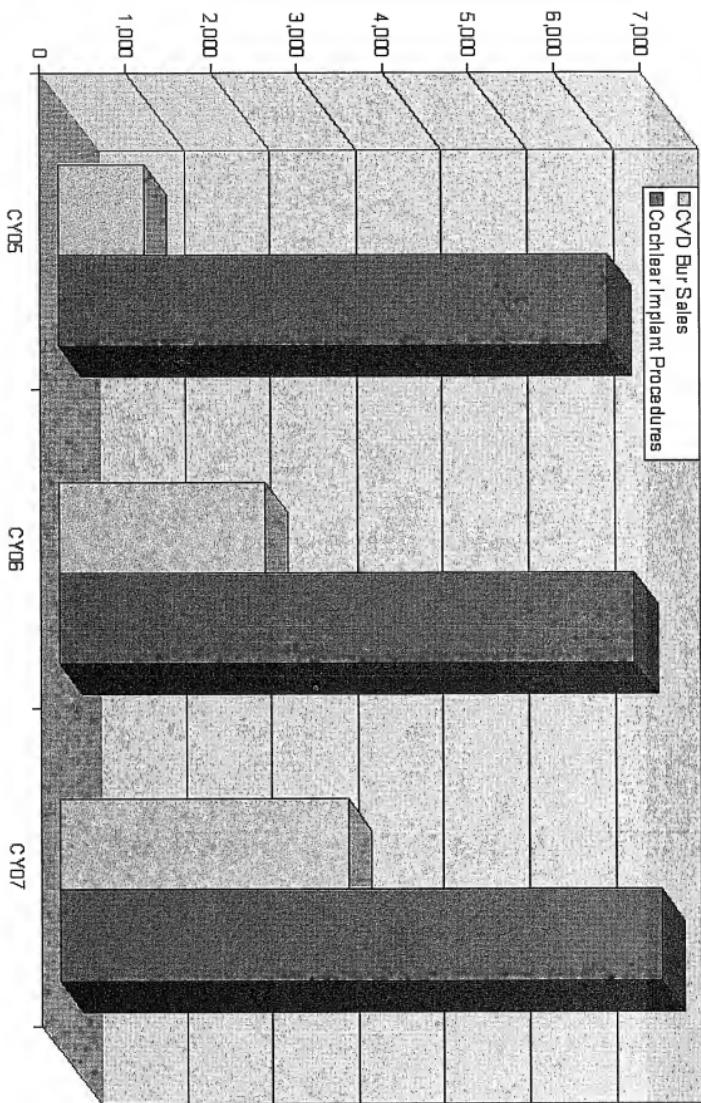


EXHIBIT D